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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,360	10/15/2001	Jean-Baptiste Dumas Milne Edwards	G-056US04CIP	4722

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,360	Applicant(s) DUMAS MILNE EDWARDS ET AL	
	Examiner Eileen O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 14-24 are pending in the instant application. Claims 1-13 have been canceled and claims 14-24 have been added as requested by Applicant in the Paper filed May 18, 2005.

Claims 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 14-22 are currently under examination.

Formal Matters

2. The Petition for an Unintentionally Delayed Claim of Priority has been considered and accepted.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising from 6 to 352 amino acids of SEQ ID NO: 437, does not reasonably provide enablement for a polypeptide comprising from 6 to 500 amino

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acids of SEQ ID NO: 437. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The protein of SEQ ID NO: 437 is disclosed in the specification as being 352 amino acids in length. Therefore, one of ordinary skill in the art would not be able to make and use a polypeptide comprising from 6 to 500 amino acids of SEQ ID NO: 437.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5.1 Claims 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Homburger et al., U.S. Patent No. 6703491, filing date March 17, 1999.

Claims 14 and 15 encompass a composition of matter comprising an isolated polypeptide comprising from 6 to 351 consecutive amino acids of SEQ ID NO: 437.

Homburger et al. disclose a polypeptide (SEQ ID NO: 58582) that comprises 7 and 6 consecutive amino acids of SEQ ID NO: 437 that are identical to amino acids 312-319 and amino acids 336-341 of SEQ ID NO: 437. Homburger et al. also teaches pharmaceutical

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compositions comprising the polypeptide and a carrier (column 8, lines 20-26). Therefore, Homburger et al. anticipates the claims.

5.2 Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Korneluk et al., U.S. Patent No. 5,919,912, July 6, 1999.

Korneluk et al. disclose a polypeptide (SEQ ID NO: 8) that comprises 6 consecutive amino acids of SEQ ID NO: 437 that are identical to amino acids 335-340 of SEQ ID NO: 437. Korneluk et al. also teaches pharmaceutical compositions comprising the polypeptide and a carrier (column 17, lines 10-15). Therefore, Korneluk et al. anticipates the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 14 and 15 encompass a composition of matter comprising an isolated polypeptide comprising from 6 to 351 consecutive amino acids of SEQ ID NO: 437, and the specification as filed did not disclose.

Maintained Rejections

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. New claims 14-22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 14-22 are drawn to a composition of matter comprising an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 437, or fragments thereof. Therefore, the claims are rejected for the same reasons as claim 2 in the previous office action.

Applicants traverse the rejection and assert that the ability of the polypeptide identified as SEQ ID NO: 437 to serve as a transcription factor or a signal transduction molecule (as disclosed in the specification) has been confirmed by Matsuda et al., in which they show that a polypeptide identical to SEQ ID NO: 437 is a transcription factor in the activation pathway of NF- κ B.

Applicants' arguments have been fully considered but are not deemed persuasive. Although the protein of SEQ ID NO: 437 may have been identified as a transcription factor, there was no specific or substantial utility disclosed, that is, no information about what DNA sequence it might bind to what gene it could activate. Although it was later identified as a transcription factor in the activation pathway of NF- κ B, this was not disclosed in the specification. The situation is analogous to identifying a protein as a G-protein coupled receptor (GPCR), based on identifying the structural characteristic of the protein having seven transmembrane domains. There are over two thousand members in the GPCR family, each with distinct activities and specificities. There are many different transcription factors, each one

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having specificity for a specific nucleic acid sequence, and the protein of the instant invention was identified based on having homology to proteins with zinc binding domains. Membership in a family of proteins does not necessarily confer a specific and substantial utility, unless the members of the family have the same or very similar activity, such as the ligases.

For these reasons the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8.1 Claims 14-22 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification were enabling of how to use the polypeptide of SEQ ID NO: 437, enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the polypeptide of SEQ ID NO: 437, the skilled artisan would clearly not know how to use polypeptides comprising fragments of the polypeptide of SEQ ID NO: 437 or fragments thereof.

8.2 Claim 14-16, 21 and 22 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants traverse the rejection at pages 8-9 of the response and submits that the

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Examiner considers the use of the transitional phrase “comprising” to result in the claiming of a large genus of polypeptides of SEQ ID NO: 437 that are not adequately described, and that the fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Applicants were not in possession of the claimed invention.

Applicants’ arguments have been fully considered but are not deemed persuasive. The claims are written encompass polypeptides that can comprise only 6 amino acids of the polypeptide of SEQ ID NO: 437. While the written description guidelines indicate that a molecule may be adequately described through a combination of structure and function, the degree of structure recited must also be considered. There is no specific cutoff for the amount of structure that is required to meet the written description guidelines, but enough structure should be recited to demonstrate possession. For example, 6 out of 352 amino acids, is only 2% of the full-length protein, and does not provide adequate structure to meet the written description guidelines. Therefore, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O’Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

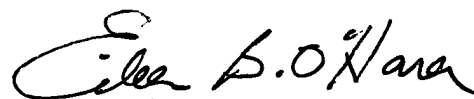
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA
PATENT EXAMINER